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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/768,744	HUNTER ET AL.	
	Examiner	Art Unit	
	Cherie M. Woodward	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,3,6,8,11-13,15,18-26 and 73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6,8,11-13,15,18-26 and 73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

1. Applicant's response and Amendments filed 29 May 2007 are acknowledged. Claims 1, 3, 6, 8, 11-13, 15, 18-26, and 73 are pending. Claims 2, 4-5, 7, 9-10, 14, 16-17, and 27-72 have been cancelled by Applicant. Claims 1, 3, 6, 8, 11-13, 15, 18-26, and 73 are under examination.

Response to Arguments/Amendments

Priority/Benefit

2. Regarding the denial of the claim of benefit to US Provisional 60/444,494, filed 31 January 2003, Applicant argues that 2 February 2004 was the first business day following Saturday, 31 January 2004, and was thus, the last day on which the instant Application could be filed and still be accorded benefit of the filing date of 60/444,494. Applicant's argument is persuasive. However, the '494 provisional is a compilation of several different documents. There are two copies, presumably a final submission and a draft of a paper for publication, which finally published as the paper that comprises the entire contents of US Provisional 60/519,074. Four other journal publications are also included in the text of the '494 provisional. However, neither of the instant co-inventors are named authors on any of these four papers. As such, no benefit can be accorded to the four papers that are not the prior work of the inventors (see also, 35 USC 102(f)). As to the work of the inventors, which take the form of the two drafts (pages 1-35) and what appears to be an invention disclosure statement (pages 35-36), nothing in the '494 provisional supports the administration of a IL-27R agonist in a method of treating a patient in need of immune suppression. The papers state that WSX-1 (also known as IL-27R) is involved in T-cell hyperactivity, but the experiments and data shown in the papers use WSX-1 -/- mice to demonstrate this phenomena in response to bacterial infections. No IL-27R agonists are taught or contemplated in the '464 provisional application. Further, the genera of IL-27R agonists of the instant claims do not support gene therapy such that a WSX-1 -/- mouse knockout model is sufficient to provide support for the presently claimed method of treatment by administering an IL27R agonist. As such, benefit to the '494 provisional is denied.

3. Regarding the denial of the claim of benefit to US Provisional 60/519,074, filed 10 November 2003, Applicant argues that the instant claims have been amended to bring the subject matter of the '074 provisional within the scope of the instant claims, as written. In support of this, Applicant points to page 10, second column of the '074 provisional. Contrary to Applicant's assertion, support is not found at page 10, second column. However, page 9, second column, of the '074 provisional discusses

implications for the role of the WSX-1 in suppressing T-cells and T-cell hyperactivity in patients in need of immune suppression. Even so, the '074 provisional does not teach agonists of IL-27R nor their administration in a method of treating a patient in need of immune suppression. Rather, the experiments and data shown in the '074 provisional use WSX-1 -/- mice to demonstrate the suppression of WSX-1 in response to bacterial infections. The studies encompassed by the '074 provisional are limited to WSX-1 knockout mice (WSX-1 -/-). The present claims recite treatment with IL-27R agonists. The genera of claimed IL-27R agonists does not encompass gene therapy such that a WSX-1 -/- mouse knockout model is sufficient to provide support for the presently claimed method of treatment by administering an IL27R agonist. As such, benefit to the '074 provisional is denied.

4. Regarding the denial of Applicant's claim for priority to "PCT/Not yet Assigned," filed 30 January 2004, in the Oath/Declaration of the instant application, Applicant raised no argument nor presented any evidence to rebut the denial of priority to the unspecified PCT application. As such, the denial of priority stands.

Objections – Specification

5. The objection to the disclosure because of informalities on page 106 related to centigrade symbols, is withdrawn in light of Applicant's amendments to the specification.

6. The objection to the use of trademarks is withdrawn in light of Applicant's amendments to the specification.

7. Rejections and objections over claims 2, 4-5, 7, 9-10, 14, and 16-17 are withdrawn as being moot in light of Applicant's cancellation of the claims.

Claim Objections

8. The objection over claims 1, 3, 6, 8, 11-13, 15, 18-26, and 73 because the specification refers to the ligand of interest as IL-27/WSX-1 throughout most of the specification and all of the examples, is withdrawn in light of Applicant's amendments to the claims.

9. The objection over claims 21, 23, and 73 related to the misspelling of "amyotrophic lateral sclerosis" is withdrawn in light of Applicant's amendments.

Claim Rejections - 35 USC § 112, First Paragraph

Enablement

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. The rejection of claims 1, 3, 6, 8, 11-13, 15, 18-26, and 73 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, related to the prevention of an immune disorder, is withdrawn in light of Applicant's amendments.

Claim Rejections - 35 USC § 112, First Paragraph

Scope of Enablement

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. The rejection of claims 1, 3, 6, 8, 11-13, 15, 18-26, and 73 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of assessing the role of IL-27R in suppressing T-cell response in WSX-1 -/- mice and enabling for a method of treating an immune disorder in a patient by administering an effective amount of an IL-27R agonist antibody or IL-27 ligand , does not reasonably provide enablement for a method of treating an immune disorder in a patient by administering an effective amount of a non-specific genus of other IL-27R agonists, is maintained for the reasons of record and the reasons set forth herein.

Applicant argues that the Examiner may be concerned about utility issues rather than scope of enablement issues (p. 15 of 26, Remarks, filed 29 May 2007). Applicant argue that they have demonstrated the importance of IL-27R in the suppression of the immune system in mice, as a standard experimental animal. Applicant argues that an agonist ligand of IL-27R is a ligand that enhances the activity of the receptor (p. 16 of 26, Remarks, filed 29 May 2007). Applicant argues that antibodies to IL-27R "can be made" that exhibit binding activity and that this can be done without undue experimentation (p. 16 of 26, middle paragraph, Remarks, filed 29 May 2007). Applicant argues that the Examiner did not

specifically point out "immune disorders" that do not reasonably belong in a Markush group comprising "immune disorders." Applicant's arguments have been fully considered, but they are not persuasive.

The instant rejection is a scope of enablement rejection under 35 USC 112, first paragraph. There is no actual or suggested utility rejection (35 USC 101) in the prosecution history of this case. Applicant's arguments regarding utility are spurious and are not related to the instant rejection. Additionally, contrary to Applicant's remarks, the Examiner provided a list of non-immune conditions that are included in Applicant's list of "immune disorders" on pages 9-10 of the Office Action of 29 November 2006. Applicant is encouraged to refer to the prior Office Action for details, as numerous non-immune conditions that are included in Applicant's Markush groups in claims 21, 23, and 73 are specifically listed by the Examiner.

Regarding Applicant's arguments that they have demonstrated the importance of IL-27R in the suppression of the immune system in mice, Applicant's "demonstration" is not at issue. The Examiner has previously recognized that Applicant used WSX-1 -/- mice (IL-27R -/- mice) to show suppression of an immune response to bacterial infections conditions including *Toxoplasma gondii* and *T. muris.* However, this showing, without more, does not provide reasonable support for Applicant's claims, as written. The claims, as written, recite a method for treating a patient [comprising] selecting a patient in need of immune suppression and administering to said patient an effective amount of an IL-27R agonist.

The specification teaches that IL-27R is involved in T-cell hyperactivity, but the experiments and data only use WSX-1 -/- mice to demonstrate this phenomenon in response to bacterial infections. In the Remarks, filed 29 May 2007, Applicants argue that antibodies can be made against IL-27R as IL-27R agonists. The Examiner agrees that making antibodies is old and routine in the art. The Examiner also agrees that antibodies can be made against any ligand or receptor that is known or disclosed. This would require a significant, but not undue, amount of experimentation. Additionally, antibodies could routinely be screened and tested to determine whether they act in an agonist or antagonist manner toward the IL-27R. In support, Matthews *et al.*, US Patent 7,074,397 (11 July 2006, benefit to 8 January 1996; previously cited in the Office Action of 29 November 2006 and cited below), teaches that thymidine incorporation assays can be used to screen antibodies for agonistic properties (column 44, lines 66-67). See also, Timans *et al.*, US Patent Application Publication 2002/0164609 A1 (publication date 7 November 2002), now US Patent 7,148,330 (12 December 2006, filed 30 November 2001), discussed at length in the Office Action of 29 November 2006, and below.

The Examiner previously stated that the singular working model of the instant application teaches methods of assessing the role of IL-27/WSX-1 in the development and regulation of resistance to

Toxoplasma gondii (see p. 111). The Examiner notes that working examples are not required. However, they are helpful in determining whether Applicant has sufficiently taught how to make or use the invention, as claimed. In the instant case, no evidence or guidance is provided to support Applicant's claims that suppression of IL-27R will treat the broad genus of claimed immune and hypersensitivity disorders.

Applicant has taught the use of IL-27 as a ligand activator of IL-27R and Applicant teaches that agonist antibodies to IL-27R can be made. The art also teaches these two species of IL-27R agonists. However, Applicant has not taught any other kinds IL-27R agonists to support the scope of the claims, which are drawn to a broad genus of IL-27R agonists. The genera of IL-27R agonists comprise antibodies, IL-27, peptide, small molecules, gene therapy directed at IL-27, IL-27R, or any part of the IL-27R signaling pathway.The immune suppressing effects of a generic, non-specific IL-27R agonist would be unpredictable in any given type of immune or hypersensitivity disorder and would require undue experimentation to make a sufficient number of representative species of IL-27R agonists and test the same for agonistic activity and effect in various immune and hypersensitivity disorders. In this regard, Applicant has only provided an invitation for further experimentation. One of skill in the art would not be able to conclude from the instant specification that a generic, non-specific IL-27R agonist would produce the claimed effect of suppressing an immune response. Applicant has not sufficiently taught how to make or use the full scope of the method as claimed.

Further, Applicant has not provided guidance as what constitutes an active fragment of IL-27 (which is comprised of a heterodimeric subunit of p28 and EBI3) (see claims 3, 8, and 15). Undue experimentation would be required to determine which portions of the heterodimeric subunit may be fragmented and retain activity. Applicant has provided no guidance whatsoever on how to do this in the instant disclosure. Additionally, Applicant has failed to provide any guidance on agonistic antibodies to IL-27R/WSX-1, inactive IL-27 fragments which retains IL-27/WSX-1 binding activity, or an antagonist antibody to IL-27R/WSX-1 which suppresses IL-27R/WSX-1 activity.

Additionally, there is insufficient guidance to support claims 25 and 26. The specification states that IL-27R is involved in the kinetics, but not the polarization of an immune response (p. 71). If IL-27R is not involved in the polarization of an immune response, it cannot be said to specifically modulate either a Th1 or a Th2 immune response.

Due to the large quantity of experimentation necessary to determine whether and which generic, unspecified IL-27R agonists would induce immune suppression in patients in need thereof, the lack of direction/guidance presented in the specification regarding same, the absence of sufficient working

examples directed to same, the complex nature of the invention, the state of the prior art establishing that antagonizing of any of the components in the receptor subunit:ligand complex (IL-27/IL-27R , alternatively known as the complex of p28/EBI3/WSX-1/gp130) should have a beneficial effect in inflammatory diseases, and the breadth of the claims which fail to recite specific IL-27R agonists that have been or are shown to agonize IL-27R such that the agonists effects immune suppression undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112, First Paragraph

Written Description

14. The rejection of claims 1, 3, 6, 8, 11-13, 15, 18-26, and 73 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, is maintained for the reasons of record and the reasons set forth herein.

Applicant argues that the data provided in the specification supports the claimed invention and shows that Applicant was in possession of the invention at the time of filing. Applicant argues that at least one member of the genus of IL-27R agonists is described, as IL-27. Applicant also argues that IL-27R agonist antibodies are adequately described in the specification. Applicant's arguments have been fully considered, but they are not persuasive.

Applicant claims a genus of IL-27R agonists that are administered in the claimed method of treating a patient in need of immune suppression. Applicant's arguments that the species of IL-27 is sufficient to describe the genus of IL-27R agonists is not supported by the facts in this case. Applicant's also argue that they have described agonistic antibodies to IL-27R, or alternatively, that one of skill in the art would be able to make, use, or describe them because antibodies may be raised against a known or disclosed receptor or ligand. Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features (see, Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 927, 69 USPQ2d 1886, 1895 (Fed. Cir. 2004); accord Ex Parte Kubin, 2007-0819, BPAI 31 May 2007, opinion at p. 16, paragraph 1).

The genera of IL-27R agonists comprise antibodies, IL-27, peptide, small molecules, gene therapy directed at IL-27, IL-27R, or any part of the IL-27R signaling pathway. While "examples explicitly covering the full scope of the claim language" typically will not be required, a sufficient

number of representative species must be included to "demonstrate that the patentee possessed the full scope of the [claimed] invention." Lizardtech v. Earth Resource Mapping, Inc., 424 F.3d 1336, 1345, 76 USPQ2d 1724, 1732 (Fed. Cir. 2005). The species of IL-27 and the subgenera of IL-27R agonistic antibodies are not adequate to describe the genus of IL-27R agonists because only two representative species have been disclosed – a naturally occurring ligand (IL-27) to its cognate receptor (IL-27R) and the subgenus of IL-27R agonist antibodies. The present claim encompasses numerous species of IL-27R agonists that are not further described.

With respect to Applicant's reliance on hypothetical Example 16 of the Written Description guidelines, "[c]ompliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed" Vas-Cath Inc. v. Mahurhar, 935 F.3d at 1563, 19 USPQ2d at 1117). While the Written Description Guidelines and hypothetical examples in the Synopsis can be helpful in understanding how to apply the relevant law, as it existed in 2001 when the Guidelines were adopted, they do not create a rigid test.

In the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus, which are IL-27R agonists. One of skill in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus.

Claim Rejections - 35 USC § 112, Second Paragraph

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. The rejection of claims 1, 3, 6, 8, 11-13, 15, 18-26, and 73 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, regarding use of a ligand as either an agonist or antagonist, is withdrawn in light of Applicant's amendments.

17. The rejection of claims 1, 3, 6, 8, 11-13, 15, 18-26, and 73 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, regarding the use of IL-27/WSX-1 and alternatively IL-27R/WSX-1, is withdrawn in light of Applicant's amendments to the claims.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

19. The rejection of claims 1, 3, 6, 8, 11-13, 15, 18-26, and 73 under 35 U.S.C. 102(a) and 35 USC 102(e) as being anticipated by Timans *et al.*, US Patent Application Publication 2002/0164609 A1 (publication date 7 November 2002) now US Patent 7,148,330 (12 December 2006, filed 30 November 2001), is maintained for the reasons of record and the reasons set forth herein.

Applicant argues the use of an IL-27R as claimed is not anticipated by Timans et al. Applicant also argues that Timans et al., is not enabled for the use of an agonist of IL-27R to affect immune suppression. Applicant's arguments have been fully considered, but are not persuasive.

. Timans *et al.*, teach the administration of an agonist of IL-D80 [p28], IL-27, or WSX-1/TCCR, "in the treatment of abnormal medical conditions, including immune disorders, e.g...inflammation..." (p. 4, col 1, paragraph 0039), those agonists include receptor [WSX/TCCR] agonists (p. 4, col 1, paragraph 0039), and agonists where the binding component is an Fv, Fab, or Fab2 fragment (p. 2, col 2, paragraph 0019). Additionally, Timans *et al.*, teach the therapeutic use of stimulatory antibodies as agonists (p. 12, col 2, paragraph 0135). Further, Timans *et al.*, teach the role of the receptor subunit WSX-1/TCCR in inflammatory responses (p. 15, col 2, paragraph 0161).

Regarding Applicant's argument that the Timan's reference is not enabling, In Re Hafner, 410 F.2d 1403, 161 USPQ 783 (CCPA 1969), held that 35 USC §112 provides that the specification must enable one skilled in the art to "use" the invention whereas 35 USC § 102 makes no such requirement as to an anticipatory disclosure (see also Rasmusson v. SmithKline Beecham Corp., 413 F.3d 1318 (Fed. Cir. 2005), as standing for the proposition that "proof of efficacy is not required for a prior art reference to be enabling"; and Impax Labs., Inc. v. Aventis Pharmaceuticals, Inc., No. 05-1313 (Fed. Cir. Nov. 20, 2006), holding that anticipation does not require actual performance of suggestions in a disclosure.

Rather, anticipation only requires that those suggestions be enabled to one of skill in the art."). Additionally, "[w]hether a prior art reference is enabling is a question of law based upon underlying factual findings." Minn. Mining & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1301 (Fed. Cir. 2002). Because Timans et al., teach administration of IL-27R receptor agonists, including agonists that have an Fab fragment, for therapeutic use in inflammatory conditions, Applicant's claims remain anticipated.

Regarding Applicant's comments related to the claim of benefit in Timans et al., Applicant notes that Timans et al., claims benefit back to August 6, 1999. Applicant argues that Timans et al., is not entitled to the date of the parent application because the data regarding IL-27R or the WSX-1 portion of IL-27R does not appear in the parent and was only added as of the filing date, November 20, 2001. It appears that Applicant is arguing both that (1) Timans et al., isn't enabled (see response to the enablement argument, above) and (2) that it is enabled as of 30 November 2001. For purposes of the instant rejection under 35 USC 102(a) the publication date of the Timans et al., PreGrant Publication of 7 November 2002 is controlling. For purposes of the instant rejection under 35 USC 102(e) the filing date of 30 November 2001 is sufficient to permit the use of the Timans et al., reference as enabled prior art. As such, the Examiner is willing to accept the 30 November 2001 filing date as the enabling date of Timans et al. However, it is still applied as prior art under 102(e) against the instant claims.

20. The rejection of claims 6, 8, 11-13, 15, and 24-26 under 35 U.S.C. 102(a) as being anticipated by Villarino *et al.*, (Immunity. 2003 Nov; 19(5):645-55), is withdrawn in light of Applicant's amendments to the claims.

It is noted that Applicant argues that the correction of priority [and benefit] should obviate Villarino et al., as an anticipatory reference under 35 USC 102(a). This argument is without merit for the reasons discussed at length above in response to Applicant's arguments regarding benefit. Although Applicant does not respond to the merits of Villarino et al., as anticipatory art, the rejection is withdrawn in light of Applicant's amendments to the claims.

21. The rejection of claims 1, 3, 6, 8, 11-13, 15, 18-26, and 73 under 35 U.S.C. 102(b) as being anticipated by De Sauvage et al., WO 01/29070 (26 April 2001) (see also US Patent Application Publication 2004/0234522 A1) is maintained for the reasons of record and for the reasons set forth below.

Applicant argues the use of an IL-27R as claimed is not anticipated by De Sauvage et al. Applicant also argues that DeSauvage et al., is not enabled for the use of an agonist of IL-27R to affect immune suppression. Applicant's arguments have been fully considered, but are not persuasive.

DeSauvage et al., teach methods for the treatment and diagnosis of immune related diseases using anti-TCCR (WSX-1) antibodies, including agonist antibodies (p. 3, last paragraph and pp. 51-56). Agonists that stimulate or enhance the activities of the TCCR (WSX-1) polypeptide are taught on page 4. Immune related diseases are defined on p. 8 as a disease in which a component of the immune system in a mammal caused, mediates, or otherwise contributes to morbidity in a mammal. Immune-mediated inflammatory diseases, non-immune mediated inflammatory diseases, infectious diseases, immunodeficiency diseases, and neoplasia are included in this definition (see, p. 8) and exemplified by disease name on p. 9. Uses of TCCR (WSX-1) are taught, beginning on p. 35. Immunostimulating components comprising TCCR (WSX-1) polypeptides used as therapeutics are taught at pp. 45 and 47. Identification of agonists of TCCR (WSX-1) are taught at pp. 48-49. Pharmaceutical compositions comprising TCCR (WSX-1) are taught at p. 58-59. Methods of treatment using TCCR (WSX-1) polypeptides and antibodies to treat various immune related diseases and conditions such as T-cell mediated diseases, including those characterized by infiltration of inflammatory cells into a tissue, stimulation of T-cell proliferation, inhibition of T-cell proliferation, increased or decreased vascular permeability or the inhibition thereof, are taught, along with exemplary disorders and conditions on pp. 59-63. See also, Example 12, pp. 79-81.

Regarding Applicant's argument that the DeSauvage et al., reference is not enabling, In Re Hafner, 410 F.2d 1403, 161 USPQ 783 (CCPA 1969), held that 35 USC §112 provides that the specification must enable one skilled in the art to "use" the invention whereas 35 USC § 102 makes no such requirement as to an anticipatory disclosure (see also Rasmusson v. SmithKline Beecham Corp., 413 F.3d 1318 (Fed. Cir. 2005), as standing for the proposition that "proof of efficacy is not required for a prior art reference to be enabling"; and Impax Labs., Inc. v. Aventis Pharmaceuticals, Inc., No. 05-1313 (Fed. Cir. Nov. 20, 2006), holding that anticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabled to one of skill in the art."). Additionally, "[w]hether a prior art reference is enabling is a question of law based upon underlying factual findings." Minn. Mining & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1301 (Fed. Cir. 2002). Because DeSauvage et al., teach a method of administering IL-27R receptor agonists, including agonist antibodies, for therapeutic use in a method of treating inflammatory conditions, Applicant's claims remain anticipated.

22. The rejection of claims 1, 3, 6, 8, 11-13, 15, 18-26, and 73 under 35 U.S.C. 102(b) as being anticipated by Bennett et al., WO 97/25425 (17 July 1997), is maintained for the reasons of record and for the reasons set forth herein.

Applicant argues that Bennett et al., does not use compositions comprising IL-27R (anti-WSX-1) antibodies to treat patients in need of immune suppression. Applicant's arguments have been fully considered, but they are not persuasive.

Bennett et al., teach compositions and methods comprising anti-WSX-1 (IL-27R) antibodies and WSX ligands (i.e. IL-27) as agonists, which are useful for activating the WSX receptor (p. 4 and p. 56). Use of anti-WSX-1 receptor agonist antibodies for the treatment of hematopoietic disorders such as leukemia, lymphoma, and anemia and for enhancement of lymphopoiesis in disorders such as HIV/AIDS and infections (p. 6). Additional therapeutic uses for WSX-1 receptor antibodies are taught on pp. 56-59. Applicant's definition of the instant patient population includes individuals with the same disorders taught by Bennett et al., as being treatable with agonist antibodies that bind the WSX receptor (IL-27R) (compare claims 21, 23, and 73). Because Bennett et al., teach a method of administering anti-WSX-1 (IL-27R) agonist antibodies for therapeutic use in a method of treating HIV/AIDS, infections, anemia (all conditions that fall within Applicant's definition of "immune disorder" (see claims 21, 23, and 73), Applicant's claims remain anticipated.

23. The rejection of claims 1, 3, 6, 8, 11-13, 15, 18-26, and 73 under 35 U.S.C. 102(e) as being anticipated by Matthews *et al.*, US Patent 7,074,397 B1 (11 July 2006, benefit to 8 January 1996), is maintained for the reasons of record and the reasons set forth herein.

Applicant argues that the '397 patent teaches the administration of the receptor itself and not receptor ligand to treat diseases such as diabetes. Applicant argues that the patient population in the '397 patent and the instant application are different because the use of IL-27R in immune disease was not know at that time. Applicant's arguments have been fully considered, but they are not persuasive.

Matthews et al., teach compositions and methods of use for agonist antibodies that bind to the WSX receptor (IL-27R) (column 3, lines 38-40, 46-47; column 14, lines 61-64, column 17, lines 14-16, column 44, line 22; column 80, lines 47-48 and 58-59; and column 45, beginning at line 36 to column 50) in conditions of insufficient receptor activation (column 44, lines 55-58) and in the treatment of hematopoietic disorders such as leukemia, lymphoma, anemia, and for enhancement of lymphopoiesis in disorders such as HIV/AIDS, infections, and malignancies (column 50, lines 58-67 to column 51, lines 1-13). Applicant's definition of the patient population includes individuals with the same disorders taught

by the '397 patent as being treatable with agonist antibodies that bind the WSX receptor (IL-27R) (see especially, column 50, lines 58-67 to column 51, lines 1-13) (compare claims 21, 23, and 73). Because the '397 patent teaches a method of using anti-WSX receptor (IL-27R) agonist antibodies for therapeutic use in a method of treating leukemia, lymphoma, HIV/AIDS, infections, anemia (all conditions that fall within Applicant's definition of "immune disorder" (see claims 21, 23, and 73), Applicant's claims remain anticipated.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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